Claims

1. A pharmaceutical composition comprising an anti-beta amyloid (Aβ) antibody or Aβ-binding fragment thereof and arginine hydrochloride (Arg.HCl), wherein the anti-Aβ antibody or Aβ-binding fragment thereof comprises an immunoglobulin heavy chain variable domain (VH) and an immunoglobulin light chain variable domain (VL), the VH and VL, respectively, comprising:

   (a) VH complementarity determining regions (CDRs), wherein

   VH-CDR1 consists of the amino acid sequence set forth in SEQ ID NO:1;

   VH-CDR2 consists of the amino acid sequence set forth in SEQ ID NO:2; and

   VH-CDR3 consists of the amino acid sequence set forth in SEQ ID NO:3; and

   (b) VL CDRs, wherein

   VL-CDR1 consists of the amino acid sequence set forth in SEQ ID NO:4;

   VL-CDR2 consists of the amino acid sequence set forth in SEQ ID NO:5; and

   VL-CDR3 consists of the amino acid sequence set forth in SEQ ID NO:6, and

   wherein the composition has a pH of 5.2 to 6.2.

2. A pharmaceutical composition comprising an anti-beta amyloid (Aβ) antibody or Aβ-binding fragment thereof, a thiol-containing antioxidant, and arginine hydrochloride (Arg.HCl), wherein the anti-Aβ antibody or Aβ-binding fragment thereof comprises an immunoglobulin heavy chain variable domain (VH) and an immunoglobulin light chain variable domain (VL), the VH and VL, respectively, comprising:

   (a) VH complementarity determining regions (CDRs), wherein

   VH-CDR1 consists of the amino acid sequence set forth in SEQ ID NO:1;

   VH-CDR2 consists of the amino acid sequence set forth in SEQ ID NO:2; and

   VH-CDR3 consists of the amino acid sequence set forth in SEQ ID NO:3; and

   (b) VL CDRs, wherein

   VL-CDR1 consists of the amino acid sequence set forth in SEQ ID NO:4;

   VL-CDR2 consists of the amino acid sequence set forth in SEQ ID NO:5; and

VL-CDR3 consists of the amino acid sequence set forth in SEQ ID NO:6, and wherein the composition has a pH of 5.2 to 6.2.

3. The pharmaceutical composition of claim 1 or claim 2, wherein the composition comprises the anti- Aβ antibody or Aβ-binding fragment thereof at a concentration of:

   (i) 50 mg/ml to 250 mg/ml;
   (ii) 75 mg/ml to 165 mg/ml;
   (iii) 150 mg/ml; or
   (iv) 100 mg/ml.

4. The pharmaceutical composition of claim 1 or claim 2, wherein the composition comprises Arg.HCl at a concentration of:

   (i) 50 mM to 250 mM;
   (ii) 75 mM to 175 mM; or
   (iii) 150 mM.

5. The pharmaceutical composition of any one of claims 1 to 3, wherein the composition comprises Polysorbate-80 (PS80), optionally wherein the composition comprises PS80 at a concentration of:

   (i) 0.01% to 0.1%;
   (ii) 0.03% to 0.08%; or
   (iii) 0.05%.

6. The pharmaceutical composition of any one of claims 1 to 5, wherein the composition comprises a buffer selected from the group consisting of histidine, acetate, succinate, and citrate, optionally wherein the composition comprises histidine, acetate, succinate, or citrate at a concentration of: (i) 10 mM to 30 mM or (ii) 20 mM.

7. The pharmaceutical composition of claim 6, wherein the buffer is histidine, optionally wherein histidine is at a concentration of: (i) 10 mM to 30 mM or (ii) 20 mM.

8. The pharmaceutical composition of any one of claims 1 to 7, wherein the composition comprises methionine, optionally wherein methionine is at a concentration of:

(i) 0.01 mM to 150 mM;
(ii) 5 mM to 15 mM; or
(iii) 10 mM.

9. The pharmaceutical composition of any one of claims 1 to 8, wherein the composition comprises sucrose, optionally wherein the composition comprises sucrose at a concentration of:

(i) 0.01% to 3% or (ii) 3%.

10. The pharmaceutical composition of any one of claims 1 to 9, wherein the composition has:

(i) a pH of 5.2 to 6.0;
(ii) a pH of 5.3 to 5.7; or
(iii) a pH of 5.5.

11. The pharmaceutical composition of claim 1, comprising:

(i) the anti-Aβ antibody or the Aβ-binding fragment thereof at a concentration of 50 mg/ml to 250 mg/ml;
Arg.HCl at a concentration of 50 mM to 200 mM;
methionine at a concentration of 0 mM to 150 mM;
histidine at a concentration of 10 mM to 30 mM;
PS80 at a concentration of 0.01% to 0.1%;
sucrose at a concentration of 0 to 3%; and
wherein the composition has a pH of 5.2 to 6.0;

(ii) the anti-Aβ antibody or the Aβ-binding fragment thereof at a concentration of 150 mg/ml;
Arg.HCl at a concentration of 150 mM;
methionine at a concentration of 10 mM;
histidine at a concentration of 20 mM; and
PS80 at a concentration of 0.05%,
wherein the composition has a pH of 5.5; or

(iii) the anti-Aβ antibody or the Aβ-binding fragment thereof at a concentration of 100 mg/ml;
Arg.HCl at a concentration of 150 mM;
methionine at a concentration of 10 mM;
histidine at a concentration of 20 mM; and
PS80 at a concentration of 0.05%,
wherein the composition has a pH of 5.5.

12. The pharmaceutical composition of any one of claims 1 to 11, wherein:
(i) the VH consists of a sequence at least 80% identical to SEQ ID NO:7 and the VL consists of a sequence at least 80% identical to SEQ ID NO:8;
(ii) the VH consists of a sequence at least 90% identical to SEQ ID NO:7 and the VL consists of a sequence at least 90% identical to SEQ ID NO:8; or
(iii) the VH consists of the amino acid sequence set forth in SEQ ID NO:7 and the VL consists of the amino acid sequence set forth in SEQ ID NO:8.

13. The pharmaceutical composition of any one of claims 1 to 12, wherein the anti-Aβ antibody comprises an immunoglobulin heavy chain and an immunoglobulin light chain, wherein:
(i) the heavy chain consists of a sequence at least 80% identical to SEQ ID NO:9 and the light chain consists of a sequence at least 80% identical to SEQ ID NO:10;
(ii) the heavy chain consists of a sequence at least 90% identical to SEQ ID NO:9 and the light chain consists of a sequence at least 90% identical to SEQ ID NO:10; or

(iii) the heavy chain consists of the amino acid sequence set forth in SEQ ID NO:9 and the light chain consists of the amino acid sequence set forth in SEQ ID NO:10.

14. Use of the pharmaceutical composition of any one of claims 1 to 13 in the manufacture of a medicament for the treatment of (i) abnormal accumulation or deposition of Aβ in the central nervous system; (ii) mild cognitive impairment; or (iii) Alzheimer's disease.

15. The use of claim 14, wherein the medicament is to be administered subcutaneously to the human subject, optionally wherein the medicament is to be administered intravenously to the human subject.

16. The pharmaceutical composition of any one of claim 2 or claim 3, wherein the thiol-containing antioxidant is selected from the group consisting of GSH, GSSG, the combination of GSH and GSSG, cystine, cysteine, and the combination of cysteine and cystine.

17. The pharmaceutical composition of any one of claim 2 or claim 3 or claim 16, optionally wherein the thiol-containing antioxidant is at a concentration of:

    (i) 0.02 mM to 4 mM;
    (ii) 0.2 mM;
    (iii) 0.4 mM; or
    (iv) 1 mM.

18. The pharmaceutical composition of claim 16, wherein the GSH is at a concentration of 0.4 mM and the GSSG is at a concentration of 0.2 mM, or wherein the thiol-containing antioxidant is the combination of cysteine and cystine, wherein the cysteine is at a concentration of 0.4 mM and the cystine is at a concentration of 0.2 mM.

19. A pharmaceutical composition of any one of claims 1 to 13 for use in therapy.